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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,128	08/29/2005	Bronislava Gedulin	0402US-UTL	7370

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Intellectual Property Department
Amylin Pharmaceuticals, Inc.
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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
09/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,128	GEDULIN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/30/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,14-21,23,25-30 and 32* is/are pending in the application.

4a) Of the above claim(s) *7 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-12,14,23,25-30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's submission filed on 06/30/2010 has been entered. Claims 1, 6, 10-12, 23, and 25-29 are amended. Claims 1-3, 5-12, 14-21, 23, 25-30, and 32 are pending. Claims 1-3, 5, 6, 8-12, 14, 23, 25-30, and 32 are under consideration. Claims 7 and 15-21 are withdrawn from consideration.

Withdrawn Objections and/or Rejections

The rejections of claims 22, 24 under 35 U.S.C. 112, first paragraph for new matter and scope of enablement and under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203) as evidenced by U.S. patent No. 5,214,066 are made moot by canceled claims.

The rejection of claims 1-3, 5, 6, 8-12, 30, and 32 under 35 U.S.C. 112, first paragraph for written description is withdrawn in view of amended claim 1.

Continuing Data

The filing data of PCT/US03/18657 provided by Applicants in is not consistent with PTO records. The FORM PTO-1390 filed by Applicants on 12/14/2004 indicates that the international filing date of PCT/US03/18657 is April 24, 2003, whereas the PTO records indicate that the international filing date of PCT/US03/18657 is 06/13/2003. Moreover,

the oath/Declaration filed on 08/29/2005 indicates that 10/518,128 was filed on December 14, 2004, whereas the PTO records indicate that the filing or 371(c) date of 10/518,128 is 08/29/2005.

It's noted that Applicants have not addressed the issue, which is noted in the previous office action.

Claim Rejections Under 35 U.S.C.§112, 1st Paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 1-3, 5, 6, 8-12, 14, 23, 25-30, and 32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating, ameliorating, or protecting from an intestinal damage, comprising peripherally administering a pharmaceutically active formulation of a PYY agonist to a human to treat or alleviate the intestinal damage, does not reasonably provide enablement for the claimed invention commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with the claims.

The rejection is maintained because the amended claim 1 still recites "prevent the intestinal damage" (line 5).

Claim Rejections Under 35 U.S.C.§102 (b)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii). Claims 23 and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) as evidenced by U.S. patent No. 5,214,066.

Balasubramaniam teaches PYY (column 2) and a pharmaceutical formulation comprising PYY (columns 14-16). The human PYY (column 2) comprises the amino acid residues recited in claims 23 and 25-29. Balasubramaniam teaches treating gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16) comprising administering PYY to a mammal, such as a human (column 6, lines 43-47). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease, which comprises an ulceration as evidenced by U.S. patent No. 5,214,066 (column 7, lines 1-7; column 1, lines 49-51). Balasubramaniam further teaches that the compounds can be administered orally or parenterally (intravenously or subcutaneously) (column 14). The daily dose in the case of oral administration is typically in the range of 0.1 to 100 mg/kg body weight, and the daily dose in the case of parenteral administration is typically in

the range of 0.001 to 50 mg/kg body weight (column 16). Thus, the teachings of Balasubramaniam meet the limitations of claims 23 and 25-29.

Claim Rejections Under 35 U.S.C.§103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). Claims 1, 2, 5, 10-12, 30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997)as evidenced by U.S. patent No. 5,214,066 (May 25, 1993).

Balasubramaniam teaches human PYY (SEQ ID NO: 1; column 2) and a PYY agonist, PYY[22-36](SEQ ID NO: 14; Table 2) and a pharmaceutical formulation comprising PYY or PYY [22-36](columns 14-16). Balasubramaniam teaches treating gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16) comprising administering PYY or PYY [22-36] to a mammal, such as a human (column 6, lines 43-47). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease. The intestinal damage caused by these gastrointestinal disorders necessarily comprises a

morphological damage, such as ulceration and those listed in claims 30 and 32. The histologic features of inflammatory bowel diseases such as ulcerative colitis or Crohn's disease comprise ulcer as evidenced by U.S. patent No. 5,214,066 (column 7, lines 1-7; column 1, lines 49-51).

Balasubramaniam also teaches that PYY inhibits gut motility and blood flow, attenuates basal and secretagogue-induced intestinal secretion in humans. Balasubramaniam further teaches that PYY plays a physiological role in regulating intestinal secretion and absorption, serving as natural inhibitors of diarrhea (column 1, lines 35-54; column 6, lines 43-67). Balasubramaniam further teaches that the compounds can be administered orally or parenterally (intravenously or subcutaneously) (column 14). The daily dose in the case of oral administration is typically in the range of 0.1 to 100 mg/kg body weight, and the daily dose in the case of parenteral administration is typically in the range of 0.001 to 50 mg/kg body weight (column 16).

Balasubramaniam fails to teach administering a PYY agonist, which consists of amino acids 16-36 of SEQ ID NO: 2 (or other amino acid sequences recited in claim 1).

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make and administer a PYY agonist consisting of the amino acids 16-36 of SEQ ID NO: 2 (or other amino acid sequences recited in claim 1) in the method of treating a gastrointestinal disorder, such as Crohn's disease (a form of

inflammatory bowel) as taught by Balasubramaniam with a reasonable expectation of success. One would have been motivated to do so because Balasubramaniam teaches that PYY and PYY functional analogs can be used to treat a gastrointestinal disorder, such as Crohn's disease (first paragraph of column 7) and that the amino acids 22-36 of PYY was the active site for interacting with intestinal PYY receptors (last line of column1 to line 2 of column 2). A PYY fragment comprising the amino acids 22-36 of PYY is expected to have the similar effect in treating a gastrointestinal disorder, such as Crohn's disease.

(iii). Claims 1, 2, 5, 10-12, 14, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) evidenced by U.S. patent No. 5,214,066 (May 25, 1993), and further in view of Dumont et al. (Brain Res. Mol. Brain Res. 26: 320-324, 1994).

Balasubramaniam teaches PYY (column 2) and a pharmaceutical formulation comprising PYY (columns 14-16). Balasubramaniam teaches treating gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16) comprising administering PYY to a mammal, such as a human (column 6, lines 43-47). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease. The intestinal damage caused by these gastrointestinal disorders necessarily comprises a morphological damage, such

as ulceration and those listed in claims 30 and 32. The histologic features of inflammatory bowel diseases such as ulcerative colitis or Crohn's disease comprise ulcer as evidenced by U.S. patent No. 5,214,066 (column 7, lines 1-7; column 1, lines 49-51).

Balasubramaniam also teaches that PYY inhibits gut motility and blood flow, attenuates basal and secretagogue-induced intestinal secretion in humans. Balasubramaniam further teaches that PYY plays a physiological role in regulating intestinal secretion and absorption, serving as natural inhibitors of diarrhea (column 1, lines 35-54; column 6, lines 43-67). Balasubramaniam further teaches that the compounds can be administered orally or parenterally (intravenously or subcutaneously) (column 14). The daily dose in the case of oral administration is typically in the range of 0.1 to 100 mg/kg body weight, and the daily dose in the case of parenteral administration is typically in the range of 0.001 to 50 mg/kg body weight (column 16).

Balasubramaniam fails to teach administering PYY[3-36].

Dumont et al. teach a PYY agonist, PYY[3-36] that binds PYY receptors (see Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administer PYY[3-36] in the method of treating a gastrointestinal disorder, such as Crohn's disease (a form of inflammatory bowel) as

taught by Balasubramaniam with a reasonable expectation of success. One would have been motivated to do so because Balasubramaniam teaches PYY and PYY functional analogs can be used to treat a gastrointestinal disorder, such as Crohn's disease (first paragraph of column 7), whereas PYY [3-36] that binds to PYY receptors is expected to have the similar effect in treating a gastrointestinal disorder, such as Crohn's disease.

(iv). Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997) evidenced by U.S. patent No. 5,214,066 (May 25, 1993) and Dumont et al. (Brain Res. Mol. Brain Res. 26: 320-324, 1994) as applied to claims 1, 2, 5, 10-12, 14, 30, and 32, and further in view of Murch et al. (U. S. Patent No. 6,046,179, Apr. 4, 2000).

Balasubramaniam and Dumont et al. in combination teach a method of treating an intestinal damage comprising an ulceration comprising administering a pharmaceutically active formulation of PYY(3-36) to a human subject, as applied to claims 1, 2, 5, 10-12, 14, 30, and 32 above.

Balasubramaniam does not explicitly teach the intestinal damage associated with ulcerative colities.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply method taught by Balasubramaniam and Dumont et al.

to treat ulcerative colities (a form of inflammatory bowel) with a reasonable expectation of success. One would have been motivated to do so because Balasubramaniam teaches that PYY can be used to treat inflammatory diarrhea, which includes Crohn's disease and irritable bowel syndrome (first paragraph of column 7), whereas symptoms of ulcerative colities and Crohn's disease are similar and are often hard to differentiate as taught by Murch et al. (column 7, last paragraph to top of column 8).

Claim objections

Claims 23 and 25-29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites "wherein said PYY agonist is selected from the group consisting of amino acids 16-36 of the amino acid sequence set out in S"Q ID NO: 2, ...", whereas claims 23 and 25-29 use the language "comprising", which does not further limit the PYY agonist of claim 1.

Conclusion

No claims are allowed.

Advisory Information

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
September 20, 2010